

AMENDMENTS TO THE CLAIMS

1. (CURRENTLY AMENDED) A method of increasing the bioavailability of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and ~~a p-gp inhibitor nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~.
2. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said azithromycin and ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ are each administered in an amount such that the combination is antimicrobially effective.
3. (ORIGINAL) A method as defined in claim 1, wherein said bioavailability increase is measured in blood serum.
4. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said ~~nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) p-gp inhibitor~~ and azithromycin are co-administered separately.
5. (CURRENTLY AMENDED) A method as defined in claim 4, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ and azithromycin are co-administered by different routes.
6. (CURRENTLY AMENDED) A method as defined in claim 5, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ is administered orally and said azithromycin is administered intravenously.
7. (CURRENTLY AMENDED) A method as defined in claim 4, wherein said azithromycin and said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ are both administered orally.

8. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and azithromycin are co-administered together in a composition.

9. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 25%.

10. (CURRENTLY AMENDED) A method as defined in claim 9, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 50%.

11. (CURRENTLY AMENDED) A method as defined in claim 10, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 75%.

12. (CURRENTLY AMENDED) A method as defined in claim 1, wherein said increase is measured as an increase in AUC relative to dosing in the absence of ~~a p-gp inhibitor~~ nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide).

13-17. (CANCELED).

18. (CURRENTLY AMENDED) A method of increasing the Cmax of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of

azithromycin and ~~a p-gp inhibitor~~ nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide).

19. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said azithromycin and ~~p-gp inhibitor~~ said nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) are each administered in an amount such that the combination is antimicrobially effective.

20. (ORIGINAL) A method as defined in claim 18, wherein said Cmax increase is measured in blood serum.

21. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and azithromycin are co-administered separately.

22. (CURRENTLY AMENDED) A method as defined in claim 21, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and azithromycin are co-administered by different routes.

23. (CURRENTLY AMENDED) A method as defined in claim 22, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is administered orally and said azithromycin is administered intravenously.

24. (CURRENTLY AMENDED) A method as defined in claim 21, wherein said azithromycin and said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) are both administered orally.

25. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and

azithromycin are co-administered together in a composition.

26. (CURRENTLY AMENDED) A method as defined in claim 18, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ is co-administered in an amount such that the Cmax of azithromycin is increased by at least 25%.

27. (CURRENTLY AMENDED) A method as defined in claim 26, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ is co-administered in an amount such that the Cmax of azithromycin is increased by at least 50%.

28. (CURRENTLY AMENDED) A method as defined in claim 27, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ is co-administered in an amount such that the Cmax of azithromycin is increased by at least 75%.

29-33. (CANCELED).

34. (CURRENTLY AMENDED) A method of increasing the concentration of azithromycin in a cell or a tissue, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and ~~a p-gp inhibitor said nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~.

35. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said azithromycin and ~~p-gp inhibitor said nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ are each administered in an amount such that the combination is antimicrobially effective.

36. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said ~~p-gp inhibitor~~

nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and azithromycin are co-administered separately.

37. (CURRENTLY AMENDED) A method as defined in claim 36, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and azithromycin are co-administered by different routes.

38. (CURRENTLY AMENDED) A method as defined in claim 37, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is administered orally and said azithromycin is administered intravenously.

39. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said azithromycin and said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) are both administered orally.

40. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) and azithromycin are co-administered together in a composition.

41. (CURRENTLY AMENDED) A method as defined in claim 34, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that said concentration of azithromycin is increased by at least 25%.

42. (CURRENTLY AMENDED) A method as defined in claim 41, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that said concentration of azithromycin is increased by at least 50%.

43. (CURRENTLY AMENDED) A method as defined in claim 42, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that said concentration of azithromycin is increased by at least 75%.

44-48. (CANCELED).

49. (CURRENTLY AMENDED) A composition comprising azithromycin and a p-gp inhibitor nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide), said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) being present in an amount such that, following administration, the azithromycin has an oral bioavailability greater than 37%.

50. (CURRENTLY AMENDED) A composition as defined in claim 49, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is present in an amount such that said oral bioavailability of azithromycin is increased by at least 25%.

51. (CURRENTLY AMENDED) A composition as defined in claim 50, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 50%.

52. (CURRENTLY AMENDED) A composition as defined in claim 51, wherein said p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 75%.

53-56. (CANCELED).

57. (CURRENTLY AMENDED) A composition which increases the Cmax of azithromycin, comprising azithromycin and ~~a p-gp inhibitor~~ nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide).

58. (CURRENTLY AMENDED) A composition as defined in claim 57, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is present in an amount such that said Cmax is increased by at least 25%.

59. (CURRENTLY AMENDED) A composition as defined in claim 58, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the Cmax of azithromycin is increased by at least 50%.

60. (CURRENTLY AMENDED) A composition as defined in claim 59, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is co-administered in an amount such that the Cmax of azithromycin is increased by at least 75%.

61-64. (CANCELED).

65. (CURRENTLY AMENDED) A composition which increases the concentration of azithromycin in a cell or a tissue, comprising azithromycin and ~~a p-gp inhibitor~~ nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide).

66. (CURRENTLY AMENDED) A composition as defined in claim 65, wherein said ~~p-gp inhibitor~~ nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide) is present in an amount such that said increase is at least 25%.

67. (CURRENTLY AMENDED) A composition as defined in claim 66, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ is co-administered in an amount such that said increase is at least 50%.

68. (CURRENTLY AMENDED) A composition as defined in claim 67, wherein said ~~p-gp inhibitor nelfinavir or said block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~ is co-administered in an amount such that said increase is at least 75%.

69-72. (CANCELED).

73. (CURRENTLY AMENDED) A kit comprising:

- (1) a therapeutically effective amount of a composition comprising azithromycin, plus a pharmaceutically acceptable carrier or diluent, in a first dosage form;
- (2) a therapeutically effective amount of a composition comprising a compound which is ~~a p-gp inhibitor nelfinavir or a block co-polymer of poly(propylene oxide) and poly(ethylene oxide)~~, plus a pharmaceutically acceptable carrier or diluent, in a second dosage form; and
- (3) a container for containing said first and second dosage forms.

74. (ORIGINAL) A kit as defined in claim 73, adapted for administration to a human.

75. (ORIGINAL) A kit as defined in claim 73, further comprising directions for the administration of said compositions.